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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/325,602 06/03/99 GALDES

A BIV-069.02

HM22/0731

PATENT GROUP  
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EXAMINER

MOEZIE, F

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

07/31/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/325,602

Applicant(s)

Galdes et al

Examiner

F. T. Moezie

Group Art Unit

1653

☒ Responsive to communication(s) filed on 06/03/99 and 10/01/99.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-2 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-2 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a method for promoting in-vitro survival of cells, classified in class 435, subclass 366, for example.
- II. Claims 5-8 and 20, drawn to a method for treating a condition in a patient, classified in class 514, subclass depending on the condition treated.
- III. Claims 5-8, drawn to a method for preventing a disorder in a patient, classified in class 424, subclass depending on the condition prevented.
- IV. Claims 9-10, 17-19 and 21, drawn to a preparation comprising a modified hedgehog polypeptide, wherein the modifying moiety is a "serol" classified in class 530, subclass depending on the elected specie.
- V. Claims 11, 12, 17-19 and 21, drawn to a preparation comprising a modified polypeptide, wherein the modifying moiety is a fatty acid, classified in class 530, subclass depending on the elected specie.
- VI. Claims 13, 14, 17-19 and 21, drawn to a preparation comprising a modified polypeptide, wherein the modifying moiety is an aromatic compound, classified in class 530, subclass depending on the elected specie.

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VII. Claims 15, 17-19 and 21, drawn to a preparation comprising a modified polypeptide, wherein the modifying moiety is an alky or cycloalkyl.

1. The inventions are distinct, each from the other because of the following reasons: Inventions IV, V, VI or VII and I, II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different processes of using that product as shown by the above claimed methods set forth in Group I, II or III invention.

Inventions I and II or III are distinct one from the other. Inventions are distinct because each invention requires a different subject, different protocol, in-vitro versus in-vivo methods for Group I and Group II or III invention. Moreover, the in-vivo methods of treating a patient are distinct because the hosts are different, different functions, different effects and different objectives are pursued in each method of treating. Additionally, a reference which would render obvious claims drawn to a method of treating a disorder in a patient may not obviate claims drawn to a method of preventing the disorder in said patient - absent ancillary evidence.

Any of inventions IV to VII are distinct one from the other. Inventions are distinct because each invention has a distinct structure, physical, chemical and pharmaceutical properties. Further, the method of making the modified polypeptides are distinct, each requiring a different

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starting material, a different set of conditions for making the modified polypeptide. Moreover, the consideration of patentability is distinct for each product, i.e., a reference which might render obvious claims drawn to one group of modified peptides may not obviate claims drawn to other group of modified peptides, absent ancillary evidence. It would be an undue burden on the examiner to search and examine all of these inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Further, the computer and the library searches are not co-extensive. Hence, the restriction requirement as set forth herein above is deemed proper.

#### **ELECTION OF SPECIES**

This application contains claims directed to the following patentably distinct species of the claimed invention:

***For Group I invention;***

- A) A method for promoting survival of neuronal cells (*generic* claim 1)
- B) A method for promoting survival of substantia nigra (claim 2)
- C) A method for promoting survival of dopaminergic cells (claim 3)
- D) A method for promoting survival of GABAergic cells (claim 4)

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***For Group II invention;***

A) A method for treating a disorder resulting from the loss of dopaminergic and/or GABAergic neurons (***generic*** claim 5)

B) A method for preventing a disorder resulting from the loss of dopaminergic and/or GABAergic neurons (***generic*** claim 16)

C) A method of treating Parkinson's disease (claim 6)

D) A method of preventing Parkinson's disease (claim 6)

E) A method for treating Huntington's disease (claim 7)

F) A method of preventing Huntington's disease (claim 7)

G) A method of treating plurality of disorders (***generic*** claim 8)

H) A method of prophylactically treating plurality of disorders ( ***generic*** claim 8).

***For any of Groups I to VII invention;***

Regardless of the invention elected, applicant is required to elect a ***specie of a modified hedgehog polypeptide***.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

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including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include (a) an election of the invention, (b) an election of a specie for the invention as outlined above and © an election of an *ultimate specie* for the generic components of the claims, as indicated above, to be examined even though the requirement be traversed (37 CFR 1.143).

An *ultimate specie* is a compound or a method of use, wherein all of the parameters of the elected specie are accounted for.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner F.T. Moezie whose telephone number is (703) 305-4508.

*F.T. Moezie*  
PRIMARY EXAMINER  
ART UNIT 1653